Summary of Comments

MaineCare Benefits Manual

Chapter II - Section 80, Pharmacy Services

Public Hearing July 14, 2004
Written comments accepted through July 25, 2004

Table of Commenters

1. Robert Morrisette, Pharmacy Group of New England
2. Jack Comart, Pine Tree Legal Assistance, Inc.
3. Joe Mackey, Long Term Care Pharmacy Alliance (Public Affairs Group)
4. Douglas Carr, Rite Aid of Maine (Perkins, Thompson, Hinckley & Keddy)
5. Mary McPherson, MaineCare Advisory Committee
6. Patrick Ende, Maine Association of Interdependent Neighborhoods (Maine Equal Justice)
7. Ann Robinson, Pharmaceutical Research and Manufacturers of America (Preti Flaherty)
8. Mark Polli, Hannaford Bros. Co.
9. Bernard Miller, Miller Drug
10. Christine Hastedt, Maine Association of Interdependent Neighborhoods (Maine Equal Justice)
11. Jim McGregor, Maine Merchants' Association and Maine Pharmacy Association

1. **Comment:** Two commenters (4, 8) objected to the use of mail order pharmacies. One commenter (4) stated that allowing mail order pharmacies to provide a 90-day supply is unfair to other retail pharmacies, would undermine the viability of the retail pharmacy network in Maine, and would harm the long term care and best interests of patients. The commenter stated that using state funds to encourage the use of mail order is "blatantly discriminatory," and that retail pharmacies have already suffered from the loss of co-payments. Two commenters (4, 8) suggested that mail order pharmacies do not provide adequate counseling to the vulnerable customers served by these programs, forcing retail pharmacies to do more. These commenters also objected that patients may receive a 90-day supply but will not use all their drugs, resulting in waste. These two commenters also stated that mail-order delivery may impact the efficacy of drugs because they are exposed to temperature extremes and "the elements." The same two commenters stated that mail-order delivery is susceptible to theft or diversion. One commenter (8) also raised concerns about "the timeliness" of prescriptions through mail order.

Response: The use of mail order providers was the subject of a separate rulemaking earlier in 2004. The Department held a public hearing on March 31, 2004 and accepted written comments through April 11, 2004. One of these commenters (4) submitted comments in that process, to which the Department responded. The rules at issue in the current rulemaking do not change the mail order provisions established through that process. Accordingly, the comments are beyond the scope of this rulemaking and no response is warranted. However, the Department notes that quality assurance standards apply in all contracts, including mail order. In addition, the issue of waste is less significant in the case of mail order, which is used mostly for maintenance drugs which are changed less often. Finally, some of the pharmacies that are impacted by the use of mail order will benefit from the financial payments made through the RPPIP program set forth in the proposed rules currently under consideration.

2. **Comment:** One commenter (4) supports the 5-brand limit and the expansion of prior authorization, but requests an opportunity for input before the further expansion of these initiatives is the subject of formal rulemaking.

Response: The Department appreciates the commenter's support. The Department will ensure that the commenter has continued opportunity for input prior to any future rulemaking through the Drug Utilization Review Committee. The Department also encourages participation in the DUR meetings where such matters are routinely discussed.

3. **Comment:** Two commenters (2, 6) questioned whether the rulemaking is flawed because the Notice of Agency Rule-Making Proposal information included with the Section 80 rulemaking package applied to the concurrent rulemaking for Maine Rx and DEL benefits, not to Section 80.

Response: The Department acknowledges that some of the printed sets of rulemaking documents provided to interested parties inadvertently included the Notice of Agency Rule-Making Proposal appropriate to Maine Rx and DEL rather than that for Section 80. The Department notes that it submitted the correct documents to the Secretary of State pursuant to the Administrative Procedures Act and posted the correct documents on its web page. The Department has taken steps to ensure that this clerical error does not occur again. Notwithstanding the mistake, the Department has not received any information that any interested party did not have actual notice or the correct information regarding the process for adopting the rules, or was in any way prejudiced in availing itself of the opportunity for comment. The public hearing for both rules were held on the same day and the mailing for both sets of rulemaking were sent to all interested parties. The Department does not regard this clerical error as a fatal defect in the notice procedures.

4. **Comment:** Three commenters (2, 5, 6) suggested that the Department automatically authorize a 34-day supply of a prescribed drug in the event that a prescriber fails to submit a completed request for prior authorization. One commenter (5) stated that the denial of a 34-day supply of medication under such circumstances would be detrimental to members. The commenter noted that factors such as inadvertent mistakes, the complexity of the prior authorization process, the need to track down the provider's administrator, and the need for a follow-up appointment with the provider can lead to significant delays meriting a 34-day temporary supply. The commenter also stated that members who are "seriously ill, frail, housebound, or with limited capacity to maneuver through any bureaucracy, cannot be expected to actively advocate for a four day turn-around on a PA." One commenter (2) stated that the federal law emergency requirement of a 72-hour supply is not limited to once per year and that, therefore, the State emergency supply should not be so limited. That commenter also asked for clarification of the "80% threshold" for refills set forth in 80.07-7(E).

Response: The proposed rules do not amend the 34-day supply provision. The proposed rules contain only one change regarding the temporary supply of drugs pending approval of a prior authorization application. That change is the addition of an automatic "one-time 4-day over-ride per calendar year per member" in the event of "vacation, lost or stolen medication, change of dosage, change of residential location, or emergency supply for long-term care facilities." Section 80.07-6(H). The automatic override created by the proposed rule is not intended to address the failure of a provider to submit a completed application for prior authorization. That issue is addressed in the sixth paragraph of Section 80.07-4(B), which is permissive and not mandatory: ". . . the Department or its designee may authorize the pharmacy provider to dispense a one-time 34-day supply of the prescribed drug." The 34-day supply provision in the sixth paragraph of Section 80.07-4(B) has not been revised in this proposed rule, so any suggestion that the 34-day period should be mandatory rather than permissive is beyond the scope of this rulemaking. The Department will continue to provide prior authorized multiple 96-hour supplies per calendar year in the event of actual emergency situations, which actually exceeds the requirement in federal law of a 72-hour supply. Finally, the "80% threshold"

means that a refill will not be allowed prior to the time that a person following the prescribed regimen for taking his or her medication would have consumed eighty percent of the medication prescribed.

5. **Comment:** One commenter (5) objected to the lack of a "clear protocol" for explaining a deficiency in a prior authorization application and the corrective action needed.

Response: The Department appreciates the comment, but notes that these rules do not change the prior authorization system. The comment is, therefore, beyond the scope of this rulemaking. The Department further notes that it has posted on the internet forms specifying the information that is required in order to grant prior authorization for any individual prescription. The Department tries to make the forms as clear as possible, while sufficiently specific to obtain the necessary information. The Department is also undertaking to review the denial notices for the most frequently denied drugs to ensure that sufficient information explaining the reason for denial is provided.

6. **Comment:** Three commenters (2, 5, 6) asked that the rules be clarified to make a distinction between the override provided by 80.07-4(B) (i.e. when the Department is unable to respond to a completed prior authorization request), and that provided by 80.07-6(H) (i.e. in cases of "vacation, lost or stolen medication, change of dosage, change of residential location, or emergency supply for long-term care facilities.")

Response: The override established in 80.07-6(H) is a "refill too soon" override. This override requires a pharmacist to select a reason code for the early refill. This allows the Department to monitor for fraud and abuse by tracking the reasons for early refills. This is a different situation from that when the Department is unable to respond to a completed prior authorization request, which is a rare occurrence.

7. **Comment:** One commenter (6) stated that there is a conflict between section 80.07-4(B) (stating that the Department "may authorize" a 34-day supply) and a letter from Chris Zukas-Lessard stating that "only 4-day's supply will be available." The commenter stated that the letter is legally invalid because it conflicts with a duly-enacted rule. The commenter called for a "clarifying letter" explaining that a 34-day supply is available when the provider has failed to submit a completed prior authorization form, notwithstanding the letter.

Response: The Department appreciates the concern expressed by the commenter. However, neither the letter referenced in the comment nor the provision cited at 80.07-4(B) is a subject of this rulemaking. The comment is, therefore, beyond the scope of the rulemaking and no changes will be made to the rule as a result of this comment.

8. **Comment:** One commenter (5) raised a concern about the process by which the Department determined that it would no longer automatically provide a 34-day supply of a drug as described above. The commenter stated that, contrary to its

state and federal mandate, the MaineCare Advisory Committee did not have an opportunity for meaningful participation in the decision to no longer authorize a 34-day supply of medication. The commenter also stated that the change was implemented without advance notice and opportunity to comment.

Response: As noted above, the 34-day provision found at Section 80.07-4(B) is not a subject of this rulemaking. The comment is, therefore, beyond the scope of the rulemaking and no changes will be made to the rule as a result of the comment.

9. **Comment:** One commenter (2) questioned whether the five brand name limit at 80.07-5(C) is necessary, noting potential confusion for members who have gone through the prior authorization process or otherwise complied with the preferred drug list to also have to comply with the five brand name limit. Another commenter (3) raised questions about any action the Department might take in the future to apply this limit to long term care pharmacies.

Response: A five-brand name limit was adopted as part of the State budget in order to achieve savings. The Department will communicate the prior authorization requirements clearly to all providers and pharmacies. The Department is working with long term care providers to establish a smooth implementation of this change. The second comment is beyond the scope of the rulemaking and no changes will be made as a result of this comment.

10. **Comment:** One commenter (2) stated that benefit management provisions found at 80.07-5(D) allow the Department to override the clinical judgment of the physician, and that the Department should not be involved in making individual medical determinations. The commenter also voiced a concern that the "education and case management" process applied in the case of certain high-cost and/or high utilizing members could "slip into a de facto lock-in without according notice and appeal rights." The commenter suggested that the use of "more explanatory" denial and deferral notices might produce a more responsive medical and member community.

Response: The Department intends the benefit management provisions to add information to the prescribing process, not to replace the clinical judgment of the prescriber. By more carefully assessing patterns of utilization and identifying opportunities to educate prescribers and participants, this will increase the cost-efficiency of the drug benefit and allow taxpayer funds to help the greatest number of persons. The case management initiative itself does not deny benefits or eligibility to any participants and does not trigger notice and appeal rights. Lock in does trigger appeal rights.

11. **Comment:** Some commenters (1, 4, 8) stated that the Maine Retail Pharmacy Provider Incentive Payment ("RPPIP") is beneficial to Maine pharmacies and should be expanded beyond rural pharmacies. One commenter (1) seeks the expansion of the payment to all pharmacies, including "independent pharmacies" in Portland and Bangor. The commenter states that "pharmacy reimbursement

cuts" and the "voluntary mail order" provision implemented this year have "seriously impacted" certain pharmacies. The commenter added that the expansion of the RPPIP to those pharmacies would help ensure that they do not have to "liquidate or close by the end of 2004." One commenter (9) states that pharmacists serving nursing homes have many expenses and receive minimal or no fees for those expenses, making it difficult for them to operate.

Response: The Department will notify all interested parties of any additional rulemaking in this area. The Department also notes that the RPPIP program is targeted at rural pharmacies because the legislature received information that rural independent pharmacies would experience the most impact from the use of mail order.

12. **Comment:** One commenter (4) sought clarification regarding what particular pharmacies in Maine may be eligible to receive RPPIP payments. Regarding 80.07-11(B), one commenter (4) sought a list of such pharmacies and information about how often that list would be updated. The commenter also asked whether it is the member or the pharmacy which must be located in the rural area for the RPPIP to apply. The commenter noted that the definition of "retail pharmacy" in the rule does not make it clear whether the RPPIP is limited to "retail drug outlets" as defined under the Board of Pharmacy rules, and raised the concern that a "mail order pharmacy, central processing center, or a central fill drug outlet" located in a rural area might be eligible under the current definitions. Another commenter (11) sought clarification of what is a rural pharmacy and pointed to limitations in the metropolitan statistical area approach.

Response: Under existing rules, only a pharmacy that accepts Medicare assignment and serves MaineCare members is eligible. These other types of entities do not meet those criteria, so would not be considered "retail pharmacies" under the definition in the rules or under the common sense understanding of the term "retail pharmacy." The Department will publish a list of the qualifying pharmacies and will periodically update that list on its web page. The Department believes that the determination of eligible rural pharmacies must be made on objective, standardized criteria, and for that reason is relying on the metropolitan statistical areas resource as the most authoritative approach. Finally, under the language of the rule, both the location of the member and the location of the pharmacy are relevant to the incentive eligibility. The Department, therefore, does not believe any revision to the rules is warranted.

13. **Comment:** One commenter (4) asked for clarification regarding the allocation of State RPPIP funds between MaineCare, DEL and Maine Rx Plus, and assurance that funds would not be "diverted" from MaineCare to DEL or Maine Rx Plus. The commenter set forth an interpretation of how the RPPIP funds would be applied between the three pharmacy benefits.

Response: The proposed rule establishes the RPPIP and the factors that are relevant to determining whether a pharmacy will receive a payment. Although the Department appreciates the comment, the allocation of RPPIP funding among these pharmacy

benefits is beyond the scope of this rulemaking. No changes will be made to the rule as a result of this comment.

14. **Comment:** One commenter (4) sought clarification of "quality pharmacy" services mentioned in the first paragraph of the RPPIP section of the proposed rule. The commenter also seeks clarification of the sentence in that paragraph: "The distance of the pharmacy from another pharmacy is considered in determining the distribution of incentive payments." In the subsequent paragraph the commenter seeks clarification of the term "each pharmacy's practices," including an explanation of what practices are relevant to the determination and whether the rating is cumulative or quarterly.

Response: Each of the phrases mentioned by the commenter appears in the introductory paragraphs to the new RPPIP section of the rules. The eight sub-paragraphs following the introductory paragraphs provide specific criteria that clarify the terms "quality pharmacy" services and "pharmacy's practices." To qualify, the pharmacy must meet the standard mentioned in the rule. The question of the distance of the pharmacy from another pharmacy is addressed in subparagraph B, which specifies a distance of "at least 10 miles," and allocates 10 percent of the calculation to that factor. The Department believes that the explanatory information is already set forth in the rule, and no changes are required as a result of this comment.

15. **Comment:** Regarding the specific factors used in the RPPIP calculation, one commenter (4) asks for clarification of the phrase "access for MaineCare members" appearing in 80.07-11(A). The commenter also seeks to know who will calculate the "percentage of unduplicated MaineCare members served," and who will provide the information regarding "PDL compliance" and the "Ratios of PA submitted to Claims Paid." The commenter also asked whether the "raw data" and "algorithm" used by the Department for the payment calculation would be disclosed so that a participating retail pharmacy could verify the calculations.

Response: The calculations will be performed by the Department or by persons working under the supervision of the Department and its personnel, based on information collected from provider pharmacies (e.g. total number of customers served) and from the Department's own records. The algorithm is a quantitative measure and is not subjective. It will be made available to interested parties, and the results of the calculation will be made available to each relevant pharmacy.

16. **Comment:** One commenter (4) asked what baseline period of time would be used, and for what period of time would the calculations for the RPPIP be made. The commenter asked whether the participating pharmacy gets separate rankings for each of the three separate RPPIP. The commenter also asked for clarification whether each individual retail licensee with a separate NABP number would get a separate ranking in the RPPIP.

Response: The baseline and time period for the rankings will be established separately in a collaborative process, and the Department welcomes input in that process. The participating pharmacies will receive separate rankings for each of the three pharmacy benefits, and the rankings will be separate for each individual pharmacy by NABP number.

17. **Comment:** One commenter (4) asked whether pharmacies had a right to appeal decisions regarding the RPPIP, and whether the Department would propose additional rules setting forth the appeal process.

Response: Although there is no formal appeal process contemplated by the rules, the Department will work with any pharmacy to resolve any discrepancy in the payment calculation.

18. **Comment:** One commenter (4) stated that it would be better if the Legislature applied the funds put into the RPPIP into the losses created by voluntary mail order instead. The commenter also stated that the RPPIP portion of the proposed rule is difficult to understand and needs to be clarified. The commenter stated that the RPPIP is "too little, too late" to assist retail rural pharmacies and that the rules will "accelerate and perpetuate the demise of rural and inner-city retail pharmacies." The commenter also called for additional assistance to rural retail pharmacies to create or enhance their delivery programs, start-up costs, and other expenses.

Response: The Department held several meetings with providers and their representatives and maintained a collaborative approach to developing these rules. The Department believes the RPPIP promises to provide some targeted relief to certain pharmacies providing vital services to members in a cost-effective fashion. The Department expects that some of the pharmacies that see a reduction in business as a result of the previously established mail order will benefit from RPPIP. The Department cannot include start-up and other unique costs in the algorithm because those costs do not enhance efficiency.

19. **Comment:** One commenter (7) stated that the RPPIP may hinder patient access to prescription drugs. Specifically, the commenter suggested a revision to Section 80.07-5(D)(2) that would "remove prior authorization as a form of intervention, thereby protecting a prescriber's patient from being indirectly punished with restricted access to the most appropriate prescription drug therapy." The commenter also objected to the use in Section 80.07-11 of "PDL compliance," "Ratios of PA's submitted to Claims Paid" and "Ratio of Early Refills and Emergency Claims Paid to Claims Paid" as factors to be considered when calculating the incentive payment. The commenter stated that it is not in the best interests of patient health to reward rural pharmacies for "restrict[ing] patient access to the best drug therapy." The commenter also stated that these incentives will "open the door to fraud and abuse . . . ." The commenter also suggested a revision to Section 80.07-5(D)(1) to "clarify that cost-related factors may be taken

into consideration, but not viewed as a qualifying factor, when identifying members and/or prescribers eligible for drug benefit management."

Response: As with existing practice, the use of prior authorization under the RPPIP will not cause a patient to be denied access to any medically necessary prescription drug, although it might reduce utilization of non-cost-effective drugs with no therapeutic advantage for a given patient. Patient health is always at the forefront of the Department's concerns, and the existing PDL and PA processes have many safeguards to protect patient health. The Department believes that existing penalties for fraud and abuse will continue to deter fraud and abuse. Finally, cost is not the only factor used in identifying members or prescribers for the drug benefit management. This management targets utilization that is not cost-effective or where the added costs come without therapeutic benefits. The Department considers all of these factors important, and rewards pharmacies according with the RPPIP for following quality assurance and cost-effective parameters set forth in policy. The Department endeavors to ensure that all patients receive all medically necessary prescribed medications. In the event that a prescriber prescribes a medication that is less cost-effective than a therapeutically comparable medication, the Department strives to determine whether the less cost-effective medication is medically necessary and if not, to steer the provider toward the more cost-effective options. The Department believes that it is appropriate to extend this approach to the RPPIP benefit so that the payments are consistent with the incentive to avoid paying for medications that are neither cost-effective nor medically necessary. No changes were made to the rules as a result of this comment.

20. **Comment:** Two commenters (3, 4) addressed the 5-brand limit program in long term care settings and/or for Non-Categorical Waiver, the expansion of prior authorization requirements, the provision of Drug Benefit Management and Intensive Benefits Management. The commenter generally supported these efforts but urged "caution" and further public input before the Department expands these programs for MaineCare, DEL or Maine Rx Plus retail pharmacy utilization.

Response: The Department will provide interested parties notice and an opportunity for comment prior to any future rulemaking.

21. **Comment:** One commenter (9) noted the expenses of delivering DME supplies such as undergarments, and of compounding prescriptions. The commenter asked to "sit down" with the Department to "come up with some additions to the policies and procedures outlined in 80.07."

Response: The Department would appreciate working together with the commenter on this issue and related matters. No changes were made to the rule as a result of this comment.